

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KD, a minor, by his parent :
and natural guardian, Kenneth Dieffenbach, and :
KENNETH DIEFFENBACH in his own right :
:
Plaintiff, :
: CIVIL ACTION NO. 07-515-***
v. :
:
UNITED STATES OF AMERICA, :
:
Defendant. :
:

PLAINTIFF'S ANSWERING BRIEF IN OPPOSITION
TO DEFENDANT'S MOTION TO DISMISS
OR IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

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NATURE AND STAGE OF THE PROCEEDING

This is a case filed under the Federal Tort Claims Act. Plaintiffs allege medical malpractice and fraud. An administrative claim was filed on behalf of both plaintiffs. After the claims were denied, plaintiffs filed suit.

SUMMARY OF ARGUMENT

1. The administrative claim was filed with the appropriate federal agency within two years of the date plaintiffs' claim accrued.
2. The minor plaintiff's father's claim was not specifically identified, but the claim that was filed includes the father's claim.

STATEMENT OF FACTS

The Government's recitation of the facts does not tell the entire story. See the attached Affidavit of Kenneth Dieffenbach. In December of 1995, when he was five years old, the minor plaintiff ("KD") was taken by his father to NIH for evaluation of a heart condition known as obstructive hypertrophic cardiomyopathy ("OHC"). While he was at NIH, KD was seen by Dr. Lameh Fananapazir. It is significant to note that before he was seen at NIH, KD had never exhibited any symptoms whatsoever relating to OHC. Despite the fact that KD was completely asymptomatic, Dr. Fananapazir informed KD's father that KD would die unless he had a pacemaker implanted. At the urging of Dr. Fananapazir, KD's father consented to the insertion of a pacemaker in his son.

What Dr. Fananapazir did not disclose to KD's father was that KD's condition did not call for the implantation of the pacemaker, and that the procedure was instead part of an experiment being conducted at NIH.

For the next three years, KD remained under the care of NIH, during which time he became quite symptomatic, and there was a progression of his symptoms dating from time the pacemaker had been implanted. Dr. Fananapazir prescribed various medications, but they did nothing to alleviate KD's worsening symptomatology. Three years after the implantation of the pacemaker, Dr. Fananapazir informed KD's father that there was nothing more that NIH could do for KD, and that KD was in need of a heart transplant.

In October of 1998, KD was admitted to Childrens Hospital in Boston ("CHOP"), where it was determined that the adverse symptomatology was being caused by the medications that had been prescribed by Dr. Fananapazir. All of the medications were stopped, and as a result, KD

showed dramatic symptomatic improvement. At the time of his discharge from CHOP, it was noted that KD met no indications for an implantable cardioverter defibrillator ("ICD"), and that KD had no identified risk factors that would qualify him as a high risk patient.

Over the next few years, KD remained under the care of CHOP. However, on September 8, 2003, KD suffered a cardiac arrest. The doctors at CHOP attributed the cardiac arrest to the pacemaker, which they said was defective. This was the same pacemaker that NIH wrongfully implanted in KD in 1995. It was decided that the pacemaker had to be removed, but the doctors determined that they could not remove the pacemaker without surgically implanting an ICD in KD.

On May 10, 2004, KD underwent open heart surgery. Following this procedure, the surgeon informed KD's father that the pacemaker should never had been implanted in the first place as there we no indications for it whatsoever. It was not until May 10, 2004 at the earliest that KD's father learned for the first time that:

- (1) In 1995, NIH had failed to provide to KD the treatment that was indicated
- (2) The treatment that KD received at NIH actually made his underlying condition worse
- (3) A pacemaker should never have been implanted in KD
- (4) Had the pacemaker not been implanted in KD, KD would not have suffered a cardiac arrest in 2003
- (5) Had the pacemaker not been implanted in KD, KD would not have needed an ICD implanted in his body in 2003
- (6) KD was part of an experiment at NIH that involved placing pacemakers in

approximately 68 children who had no symptoms of heart disease

(7) Instead of telling the truth, Dr. Fanananpazir used scare tactics to convince KD's father to permit NIH to implant a pacemaker in KD

ARGUMENT

I. THE LEGAL STANDARD FOR A MOTION TO DISMISS

In determining the legal standard applicable to this case, the first step is to consider whether the Government's motion is a Rule 12(b)(6) motion or a Rule 12(b)(1) motion. In a case directly on point, the Third Circuit has indicated that when the issue before the Court is the accrual of a medical malpractice action under the FTCA, that is not a jurisdictional issue but rather a failure to state a claim issue. *Medina v. City of Philadelphia*, 05-2908, (3rd Cir. 2007). Thus, the Government's motion to dismiss is under Rule 12(b)(6).

The purpose of a motion to dismiss pursuant to Rule 12(b)(6) is to test the legal sufficiency of a complaint. *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957); *Strum v. Clark*, 835 F.2d 1009, 1011 (3d Cir. 1987). In reviewing a motion to dismiss for failure to state a claim, "all allegations in the complaint and all reasonable inferences that can be drawn therefrom must be accepted as true and viewed in the light most favorable to the non-moving party." *Strum*, 835 F.2d at 1011; see also *Jordan v. Fox, Rothschild, O'Brien & Frankel*, 20 F.3d 1250, 1261 (3d Cir. 1994). A court may dismiss a complaint for failure to state a claim only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations. *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984); *Jordan*, 20 F.3d at 1261. *Cox v. Shiflet*, Civil Action No. 04-1388 JJF D. Del. 2004. Further, as the moving party, the Government has the burden of proof. *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir. 1991).

The Government has attached medical records to its brief, and relies on those records to support its argument as to when plaintiff's claim accrued. As these medical records are not part of the record in this case, the Court should not consider those records.

II. The Administrative Claim Was Timely Filed

Under the Federal Tort Claims Act (“FTCA”), plaintiff was required to file his claim with the appropriate federal agency, in this case the NIH, within two years of the date plaintiff’s claim accrued. Plaintiff’s administrative claim was filed March 24, 2004, and so the question raised by the Government’s motion is whether plaintiff’s claim accrued before or after March 28, 2004.

Over the last 25 years or so, it appears that most of the federal courts which have addressed the question of when a medical malpractice claim accrues start with *United States v. Kubrick*, 444 U.S. 111 (1979), a Third Circuit case. The *Kubrick* rule is that a medical malpractice claim against the Government does not accrue until (1) the plaintiff knows or has facts that would lead a reasonable person to know, that he has been injured, and (2) the plaintiff knows who caused his injury. *Kubrick*, 444 U.S. at 122. When the Government raises the statute of limitations, it is the Government who has the burden of proof to establish that the plaintiff knew or should have known of the injury and its cause more than two years before the administrative claim was filed.

Hughes v. United States, 263 F.3d 272 (3d Cir. 2001).

In support of its motion that the plaintiff’s administrative claim was filed too late, the Government incorrectly concludes that the latest time that the statute in this case began to run was when the minor plaintiff’s pacemaker was removed on September 15, 2003. Defendant argues that any complications relating to implantation of the pacemaker would have been apparent at the time it was removed, and that no complications were noted at that time. As indicated above, the Government’s argument should not be considered because it is based entirely on medical records which are not part of the record. Even if the records are considered, they do not support the Government’s argument. Contrary to what the Government suggests, the

fact that no complications were noted as late as September 15, 2003 supports the plaintiff's argument that as of that date, he did not even know that he had been injured, let alone know who had inflicted the injury on him. It was not until KD had open heart surgery on May 10, 2004 that he learned that an injury had been inflicted on him, and it was not until even later that he learned that it was the Government that caused the injury. And, because plaintiff's administrative claim was filed on March 28, 2006, it was filed well within the two year statute of limitations.

In *Kubrick*, the plaintiff's claim involved an identifiable injury caused by the treatment administered by the doctors, i.e., the negligent administration of a certain drug. Since *Kubrick* was decided, the Third Circuit has elected to distinguish that kind of claim from an action based on a failure to diagnose, treat or warn. In *Hughes v. United States*, 263 F.3d 272 (3d Cir. 2001), for example, the plaintiff's hands and legs were amputated after he had an allergic reaction to heparin which led to gangrene. The *Hughes* Court found that the plaintiff's injuries occurred not only because of his allergic reaction to the drug, but because the doctors failed to diagnose and treat his reaction to the drug. Differentiating injuries caused by affirmative malpractice from injuries caused by a failure to diagnose, treat or warn, the Court noted that it is often difficult for a plaintiff to determine the genesis of an injury resulting from a doctor's omissions, and a failure to identify and treat a latent condition may not become manifest to the patient until years later at the onset of a serious malady. Thus, the absence of a diagnosis or the failure to render an accurate diagnosis is, by its very nature, often elusive and difficult to pin down.

In *Green v. United States*, No. 05-1298, Third Circuit (decided March 31, 2006), the plaintiff had no reason to suspect an iatrogenic cause of his injury in light of the assurances he had received from the VA doctors that his hip X-Rays were normal. The plaintiff was led to

believe that his dislocations and pain were the normal results of surgery rather than the failure of the doctors “to recognize and correct the improperly positioned prosthesis.”

In much the same way as the plaintiffs in *Hughes* and in *Green*, KD’s father was led to believe that KD’s worsening condition was caused by his underlying obstructive hypertrophic cardiomyopathy. KD’s father was misled into believing that the pacemaker was urgently required, and he had no way of knowing that the pacemaker should never have been implanted in the first place.

It cannot be emphasized enough that this claim involves allegations that the NIH deliberately concealed the truth about KD’s condition, deceived KD’s father about the appropriate treatment for his son, and failed to disclose the true purpose behind the treatment which the NIH strong-armed KD’s father into consenting to.

In case of fraudulent concealment, it is the rule in most jurisdictions that if the one who practices the fraud conceals material facts and thus prevents discovery of his wrong or of the fact that a cause of action has accrued against him, the limitations period will not begin to run until the facts are discovered, or, in the exercise of reasonable diligence, should have been discovered. *Holmberg v. Armbrecht*, 327 US 392, 397, 66 S Ct 582, 90 L ed 743 (1946). "This equitable doctrine is read into every federal statute of limitations"

III. The Complaint Should Not be Dismissed As To Kenneth Dieffenbach

The fact that the administrative claim form submitted to NIH did not list a separate claim on behalf of KD’s father does not mean that the father’s cause of action should be dismissed.

The purpose of the administrative claim requirement is to provide notice to the relevant federal agency of claims, not to put up a barrier of technicalities to defeat claims.

This Court does not believe that was ever Congress’s intent to permit every nuance ... to undermine or frustrate the purpose of the notice

requirement. *** Since the government was preparing for a claim from the administrator of the state, they are not prejudiced by a claim from the parents because the standards of law are the same, even though the theories of recovery are different. *Munger v. United States*, 116 F. Supp. 2d 672 (D. Md. 2000)

CONCLUSION

For the reasons set forth above, it is requested that the Government's motion to dismiss be dismissed.

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